

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant/Appellant: James P. Elia ) Docket No.: Case No. 1  
 )  
Serial No. 09/064,000 ) Group No.: 1646  
 )  
Filed: April 21, 1998 ) Examiner: Elizabeth C. Kemmerer, Ph.D.  
 )  
Title: METHOD FOR GROWTH )  
OF SOFT TISSUE )

MAIL STOP APPEAL BRIEF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPELLANT'S APPEAL BRIEF**

**CERTIFICATE OF MAILING**

I hereby certify that the attached APPELLANT'S APPEAL BRIEF was deposited, in triplicate, as First Class Mail, in an envelope addressed to: Mail Stop APPEAL BRIEF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 this 12th day of April, 2005.

Dated: 4/12/05

Gerald K. White

Printed Name: GERALD K. WHITE

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### **REAL PARTIES IN INTEREST**

The real parties in interest in the instant appeal are Assignees, Dental Marketing Specialists, Inc., an Arizona corporation, 9377 E. Bell Road, Suite 385 Scottsdale, Arizona 85260, and Jerry W. Bains and Salee C. Bains Irrevocable Trust, 9013 Red Lawrence Drive, Carefree, Arizona 85377. Subsequent to the assignment recordal for the instant application, the address of Dental Marketing Specialists, Inc., changed to 7364 East Crimson Sky Trail, Scottsdale, Arizona 85262. Also subsequent to the assignment recordal for the instant application, the address of Jerry W. Bains and Salee C. Bains Irrevocable Trust, changed to 39096 N. 102<sup>nd</sup> Way, Scottsdale, Arizona 85262.

## **RELATED APPEALS AND INTERFERENCES**

There are two related appeals known to Applicant, Appellants' legal representative, or Assignee, which may directly affect or be directly affected by or may have a bearing on the Board's decision in the pending appeal.

First, an appeal from the Final Rejection of June 1, 2004, in patent application Serial No. 09/794,456 was filed on November 23, 2004; and an Appeal Brief was filed on March 25, 2005.

Second, an appeal from the Final Rejection of December 9, 2004, in patent application Serial No. 09/836,750 was filed on April 7, 2005.

The instant application is the parent application of application Serial Nos. 09/794,456 and 09/836,750.

In the instant application, a Petition under 37 C.F.R. §1.113 to Director of Group 1600 was filed on November 5, 2004, seeking clarification and resolution of an objection made by the Examiner in the Final Rejection. To date, Appellant has not received an answer to such Petition. Status Letters regarding the Petition were filed on February 1, and on March 30, 2005. To date, Appellant has not received an answer to either Status Letter.

There are no related interferences known to Applicant, Appellants' legal representative, or Assignee, which will directly affect or be directly affected by or having a bearing on the Board's decision in the pending appeal.

**STATUS OF CLAIMS**

Claims 1-381 are cancelled.

Claims 382-388, the only claims remaining in the application, stand finally rejected, and are included in the instant appeal.

**STATUS OF AMENDMENTS**

No amendment has been made or entered subsequent to the Final Rejection of  
October 18, 2004.

## **SUMMARY OF INVENTION**

Appellant's invention, in its broadest form, is set forth in independent claim 382. Such claim involves a method for producing a desired soft tissue in the body of a human patient by placing cells in the body, forming a bud in the body, and growing the desired soft tissue from the bud. Support for this claim may be found in the specification at page 20, lines 10-16; page 21, lines 4-6, 14, and 15; page 31, lines 3 and 18-26; page 37, lines 19-22 and 26; page 38, line 21 to page 42, line 27 (Examples 1-17); page 44, lines 19-29; page 45, lines 1-4 and 17-28; page 46, lines 3-16; page 47, line 22; page 48, lines 2-8 and 13-15; page 50, lines 2-5; page 52, lines 26-27; page 55, lines 14 and 15; and page 61, lines 8-10.

Dependent claims 383 and 384 further require the cells to be multifactorial and non-specific and to be stem cells, respectively. Support for these claims may be found in the specification at page 37, lines 19-22; page 48, lines 13-15; and page 50, lines 2-5.

Dependent claims 385, 386, and 388 further require the formation of a new artery. Support for these claims may be found in the specification at page 45, lines 1-4; page 46, lines 3-16; page 47, line 22; page 48, lines 2-8 and 13-15; and page 50, lines 2-5.

Dependent claim 387 further requires that the soft tissue comprise mesodermal tissue. Support for this claim may be found in the specification at page 20, lines 10 and 11.

## ISSUES

1. Whether the Examiner's construction of finally rejected claims 382-388, which requires reading extraneous language into the claims, constitutes reversible error.
2. Whether the Examiner's rejection of claims 383 and 384, for failure to satisfy the definiteness requirement of 35 U.S.C. §112, second paragraph, constitutes reversible error.
3. Whether the Examiner's rejection of claims 382-388, as applied to a living organism, for failure to provide either a credible, specific and substantial asserted utility or a well established utility under 35 U.S.C. §101 constitutes reversible error.

### **GROUPING OF CLAIMS**

Each ground of rejection set forth in the Final Rejection involves a group of two or more claims. Appellant states that the claims in each rejection stand or fall together.

## ARGUMENT

Appellant notes that the Examiner, after entering Applicant's amendment filed August 18, 2005, which cancelled all pending claims and added new claims 382-388, made an objection to said new claims 382-388 as allegedly reading on non-elected inventions and entered a final rejection against claims 382-388 thereby cutting off prosecution on Applicant's part. Applicant filed a Petition to the Director of Group 1600 on November 5, 2004, in an attempt to resolve such objection.<sup>1</sup> Status Letters regarding the Petition were filed on February 1, and on March 30, 2005. To date, Appellant has not received an answer to the Petition or either Status Letter.

As will be seen from the Petition, Appellant has been placed in an untenable position by the delays incurred during prosecution of the instant application by the Patent and Trademark Office (PTO), including the further delay incurred while awaiting a response to the Petition. Such delays have caused the time to meaningfully respond to the final rejection to diminish, the potential patent term to erode, and the costs (extension and appeal fees) to increase. In view of these circumstances, Appellant believes that there is no procedural alternative but to file the instant Appeal.

Appellant further points out that claims 382-388 have not been rejected in view of prior art, and for good reason. While Appellant understands that the Examiner's objection is not appealable, the instant appeal has been taken for review of the correctness of the Examiner's refusal to allow the claims in issue by finally rejecting claims 383 and 384 for "indefiniteness" and claims 382-388 for "lack of utility."

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<sup>1</sup> A copy of the Petition is attached hereto as Exhibit A for the Board's convenience.

Further, Appellant believes that the Examiner's entry of the amendment canceling all pending claims and adding new claims 382–388 is tantamount to an admission that the subject matter of these new claims falls within the scope of the elected invention and, perforce, renders any objection thereto moot.

**Claim Construction accorded Claims 382-388 by the Examiner**

The Examiner on page 5 of the Final Rejection states that claims 382-388 are under examination to the extent that they read on Appellant's elected invention for a method of using "a living organism" for producing soft tissue. Appellant points out that cells are sub-species of the elected genus "living organism" and that stem cells are species of cells. The claims in issue are expressly drawn to such sub-species and species, not the genus. It is improper for the Examiner to enter claims to the sub-species and species and subsequently treat such claims as though they called for the genus. It is the words and terms of a claim that determine the scope of invention sought, and Appellant is not aware of any authority that allows the Examiner to read unintended words into a claim and reject the claim based on such a claim construction. Appellant believes that it was error for the Examiner to reject the claims in issue based on a construction other than that intended and set forth by the express words of the claims. cf. In re Priest, 582 F.2d 33, 199 USPQ 11 (CCPA 1978).

**Rejection of Claims 383 and 384 Under 35 U.S.C. §112, second paragraph**

Claims 383 and 384 stand finally rejected under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as his invention.” The Examiner states that the basis for the rejection is found in the Office Action of June 3, 2004, which dealt with the invention defined in claims that were cancelled.

The specification clearly describes that the multifactorial and non-specific cells contemplated by the claims on appeal are stem cells and germinal cells (page 37, line 19) and further describes such cells as being pluripotent (page 50, lines 2 and 3). Those skilled in the art are familiar with stem cells and understand that pluripotent stem cells are non-specialized cells that are capable of developing into any of the three major tissue types: endoderm, mesoderm and ectoderm and, thusly, are capable of forming a variety of soft tissues and organs. The specification also specifically describes using “living stem cells” which are harvested from “the bone marrow, the blood of the patient, or from cell cultures” (Example 15, pages 41 and 42).

For the first time the Examiner on page 6 of the Final Rejection of October 18, 2004 asserted that, “Despite significant searching of the literature databases by the Examiner, no art was found that uses the term ‘multifactorial and non-specific’ to describe any cells of living organisms.” Presumably, by using the term “art” the Examiner is referring to patent and other literature databases. This is not the standard for determining definiteness under the purview of the statute. A cursory review of the internet using the Google search engine by Appellant’s counsel revealed that those in the medical arts would readily understand that pluripotent stem cells are capable of forming multiple soft tissues including an artery and muscle and it is their “versatility and nonspecifically” that gives them the potential to have therapeutic applications.<sup>2</sup> Further,

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<sup>2</sup> <http://www.meta-library.net/biogloss/stemcel-body.html> (attached hereto as Exhibit B)

it is clear that Appellant used the term “living organism” to describe a living thing i.e., living matter, such as cells in general and living stem cells in particular (Example 15, pages 41 and 42). That cells, such as stem cells, are living organisms is so well understood by those skilled in the medical arts that the PTO should take Official Notice of this fact. In any event, the Board is referred to the Petition where evidence that the Institutes of National Health (hereinafter “NIH”) consider that cells are living organisms is presented. The definition of “cell” provided by NIH includes the statement that, “all living organisms are made of one or more cells.” Such information should conclusively resolve this matter.

Appellant attempted to address the issue of the meaning of the terms “multifactorial” and “non-specific” by filing a Fifth Supplemental Information Disclosure Statement (hereinafter “IDS”) on October 21, 2004 -- three days after the Final Rejection was mailed. Appellant had not received the Final Rejection when the IDS was filed, and thus the respective communications crossed in the mail. Appellant provided this same information to the Examiner in the other applications mentioned in the Related Appeals and Interferences section of this Brief and desired to further complete the record in the instant application. To date, the Examiner has not provided any indication whether the IDS has been entered into the record. The IDS contains information that is relevant to meaning of the terms “multifactorial” and “non-specific.” Appellant includes a copy of such IDS (attached hereto as Exhibit C). This IDS should be considered by the Board because it contains the very information that the Examiner, for the first time in the Final Rejection, indicated could not be found in the “art”, and thus responds to the Examiner’s newly raised comment.

In view of the above evidence and accompanying remarks, Appellant submits that the Board should find that the rejection under 35 U.S.C. §112, second paragraph was erroneous and reverse such rejection.

**Rejection of Claims 382-388 Under 35 U.S.C. §101 and §112, first paragraph**

Claims 382-388 stand finally rejected under 35 U.S.C. §101, “because the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility” and under 35 U.S.C. §112, first paragraph, “as not supported by either a credible, specific and substantial asserted utility or a well established utility.” Thus, claims 382-388 stand rejected for “lack of utility” under Sections 101 and 112 of the statute. Appellant disagrees that the utility requirement of the statute has not been met.

It is appropriate to consider the correctness of these rejections jointly because a determination that the Section 101 rejection is improper necessarily invalidates the Section 112 grounds. See MPEP Section 2164.07. All that Sections 101 and 112 require is that some use be defined in the specification and that such use be provable. The specification clearly discloses a specific utility for the claimed invention on page 46 by describing using cells to grow new arteries and new muscles in a human patient. The Strauer publication of record constitutes evidence which shows and establishes utility for Appellant’s claimed invention. Moreover, the Examiner has admitted on page 11, lines 16-18 of the June 3, 2004 Office Action that, “Strauer report that administration of bone marrow cells appeared to promote myocardial regeneration and neovascularization.” Such admission was incorporated into the Final Rejection.

The facts of the present case clearly evince that Appellant 1) has disclosed a specific utility for the claimed invention; and 2) has provided credible evidence in the form of the Strauer publication in support of the asserted utility. On the other hand, as demonstrated above, the Examiner has admitted the asserted utility and has not presented any evidence that would cause one skilled in the art to doubt Appellant's asserted utility.

The standard for establishing the required statutory utility under current law is that the evidence, considered as a whole, be sufficient for one of ordinary skill in the art to conclude that the asserted utility would be more likely true than false. See In re Irons, 340 F.2d 974, 978, 144 USPQ 351, 354, (CCPA 1956). Appellant submits that such a burden has been met on this record.

In view of the above discussion, Appellant submits that the Examiner has not met the burden of establishing a reasonable basis to support the conclusion of lack of utility of the inventions called for by claims 382-388 and, perforce, the rejections for "lack of utility" under Sections 101 and 112 of the statute must be reversed under current law.

**CONCLUSION AND RELIEF SOUGHT**

Reversal of the Final Rejection of claims 382-388 and an indication of the patentability of said claims over the rejections of record is respectfully requested.

Respectfully submitted,

Dated: April 12, 2005



Gerald K. White  
Reg. No. 26,611  
Attorney for Appellant

Dated: April 12, 2005



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Attorney for Appellant

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## **APPENDIX**

Claims on Appeal

Exhibits

- Exhibit A Petition to the Director of Group 1600, dated November 5, 2004
- Exhibit B Google search, <http://www.meta-library.net/biogloss/stemcel-body.html>
- Exhibit C Fifth Supplemental Information Disclosure Statement, dated 10/21/04

**CLAIMS ON APPEAL**

Claim 382                   A method for producing a desired soft tissue in a body of a human patient comprising:

- (a) Placing cells in said body of said human patient;
- (b) Forming a bud in said body of said human patient; and
- (c) Growing said desired soft tissue from said bud.

Claim 383                   The method of claim 382, wherein said cells are multifactorial and non-specific.

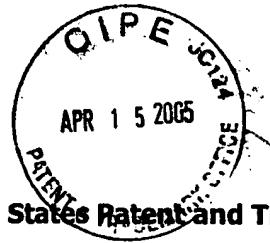
Claim 384                   The method of claim 383, wherein said cells comprise stem cells.

Claim 385                   The method of claim 382 further comprises forming a new artery.

Claim 386                   The method of claim 383 further comprises forming a new artery.

Claim 387                   The method of claim 382, wherein said soft tissue comprises mesodermal tissue.

Claim 388                   The method of claim 382, wherein said soft tissue comprises an artery.



In The United States Patent and Trademark Office

In re application of: James P. Elia

Group No.: 1646

Serial No.: 09/064,000

Examiner: Elizabeth C. Kemmerer, Ph.D.

Filed: April 21, 1998

For: METHOD FOR GROWTH OF SOFT TISSUE

**MAIL STOP AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**ATTN: DIRECTOR OF GROUP 1600**

1. Transmitted herewith is a Petition to Director of Group 1600 for this application.

2. Applicant is a small entity.

3. Fee Payment Being Made at This Time

Enclosed  
 filing fee (Petition to Director)

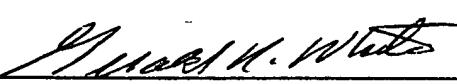
Total Fee paid at this time \$ 130.00

4. Method of Payment of Fees

Check No. 766 in the amount of \$ 130.00

**NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).**

Reg. No.: 26,611

  
Signature of attorney

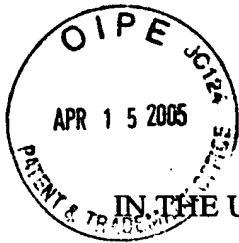
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: James P. Elia )  
Serial No.: 09/064,000 ) Group Art Unit: 1646  
Filed: April 21, 1998 ) Examiner: Elizabeth C. Kemmerer, Ph.D.  
For: METHOD FOR GROWTH )  
OF SOFT TISSUE )

**PETITION UNDER 37 C.F.R. §1.113 TO DIRECTOR OF GROUP 1600**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Sir:

This Petition is filed under 37 C.F.R. §1.113 seeking review and resolution of the Examiner's objection to claims 382-388, all the claims in the subject application. Petitioner prays for relief in the form of the withdrawal of such objection and the issuance of a complete action on the merits of the invention of claims 382-388.

**BASIS FOR PETITION**

Petitioner believes that the Director's review of Examiner's objection to claims 382-388 is justified based upon the Examiner's misunderstanding of Petitioner's invention, which is manifested by the Examiner's mischaracterization and lack of understanding of the terms "living organism," "multifactorial," and "nonspecific" as they relate to the claimed invention.



The Examiner's entering of claims 382-388, and then effectively not examining the subject matter of such claims, renders it difficult, if not impossible, to respond to the Examiner's final rejection. The Examiner erred procedurally by treating the newly entered claims as if these claims were drawn to subject matter contained in canceled claims. Petitioner believes that any appeal to the Board of Patent Appeals and Interferences would necessarily raise jurisdictional issues and result in a remand for clarification of the status of claims 382-388. Accordingly, resolution of the objection by the Director of Group 1600 is a prerequisite to the further, meaningful prosecution of the instant application.

#### STATUS OF THE APPLICATION

Claims 382-388 (attached hereto as Exhibit A) are the only claims pending in the subject application. These claims were first presented in Petitioner's response of August 18, 2004, and were entered by the Examiner. In the Examiner's October 18, 2004 Final Office Action, these claims were finally rejected on technical grounds and also were objected to for allegedly reading upon non-elected inventions. The Examiner did not enter a prior art rejection against any claim. Petitioner believes that the Final Rejection is premature because no action, let alone a first action, was made on the merits of the subject matter of claims 382-388.

#### PROSECUTION HISTORY OF THE APPLICATION

The first action on the merits for the instant application was a rejection issued by Examiner Nicholas D. Lucchesi on May 27, 1999. Following Petitioner's response filed December 16, 1999, Examiner Lucchesi issued a non-Final Rejection on August 16, 2000. Petitioner responded to such rejection in an Amendment dated February 14, 2001. Examiner Lucchesi did not respond to this Amendment and instead is believed to have transferred

jurisdiction of the application to Examiner Elizabeth C. Kemmerer sometime during the summer of 2003. The two and one-half year period of inaction while the case was under Examiner Luccehs's jurisdiction included a six-month suspension of prosecution. On September 15, 2003, Examiner Kemmerer acted on the application for the first time by making a 26-way restriction requirement on previously cancelled claims. Petitioner responded to such restriction requirement on September 18, 2003 by pointing out that the claims subject to the restriction requirement had been canceled and submitted a copy of the Amendment containing the pending claims. On November 19, 2003, the Examiner vacated the September 15, 2003 restriction requirement and made a two-part species restriction. Petitioner elected the species drawn to organic matter in the response of December 17, 2003. In the February 24, 2004 action, the Examiner withdrew the original restriction requirement because of an apparent lack of understanding of the term "organic matter." The Examiner erroneously believed that organic matter was "limited to small organic molecules, such as ring structures and not encompassing species listed in the requirement, such as the growth factor polypeptides of species d) – n)." Petitioner remains at a loss to understand how such an interpretation could have been placed on the term "organic matter" because no such ring-type structure was disclosed in the specification. Moreover, Petitioner does not understand how the Examiner could determine that polypeptides are not organic matter. On March 3, 2004, Petitioner elected to prosecute claims to the sub-generic term or species, "living organism." Petitioner also identified claims readable on such inventions as including claims to multifactorial and/or nonspecific living organisms. Multifactorial and/or nonspecific are disclosed in the specification as characteristics of growth factors comprising cells, such as stem cells. Please see page 37, lines 19-25 and page 49, line 28 through page 50, line 6. In a subsequent Office Action dated June 3, 2004, the Examiner changed the restriction requirement yet another time by joining species o) –bacteria and species q) –virus into species c)

-living organism and then rejected all of the claims under 35 U.S.C. §101 and §112. During such rejection, the Examiner contended that the terms “multifactorial” and “nonspecific” were not used to describe living organisms in the art and that a living organism included bacteria and virus or any other living organism which promotes tissue growth and that a stem cell is not a living organism. Thus, in the Office Action the Examiner excluded an embodiment (multifactorial and nonspecific growth factor, such as a stem cell) of the disclosed invention that was elected by Petitioner. Petitioner responded to the June 3, 2004 Office Action on August 19, 2004 by pointing out the Examiner’s erroneous understanding of the above terms and, in an effort to obtain a first action on the merits of its elected invention, canceled the prior claims and presented a new set of claims. Petitioner’s responses (amendments) have consistently constituted a narrowing from the original growth factor genus while staying within the scope of the elected invention. Petitioner expected that such submissions would provoke a legitimate action on the merits. Instead, the Examiner issued the Final Rejection on October 18, 2004, which basically repeated the errors of the previous Office Action.

Including Examiner Lucchesi’s inaction and six-month suspension and Examiner Kemmerer’s procedural Office Actions that involve primarily restriction requirements, rather than actions on the merits, over three and one-half years have passed since the last Office Action on the merits was issued. The three-year term extension guarantee, which applies to later-filed applications, does not apply to the instant application because Petitioner’s April 21, 1998 filing date falls between June 8, 1995, and May 28, 2000. Thus, perforce, Petitioner has already been severely prejudiced in term length by the long administrative delay by the PTO between the February 15, 2001 response and the Office Action of October 18, 2004. Furthermore, this delay has been compounded by the outstanding Final Rejection, which does not appear to treat the elected invention.

**EXAMINER'S OBJECTION TO CLAIMS 382-388**

In objecting to claims 382-388, the Examiner stated that the claims read on non-elected inventions. As will be demonstrated below, the claims, in fact, read upon the invention elected by Petitioner; and the Examiner's position is flawed due to a fundamental lack of understanding of and a mischaracterization of the terms "multifactorial" and "nonspecific" as well as "living organism." Petitioner believes that the Examiner's objection is inextricably linked to a series of restriction requirements and a failure of the Examiner to consider the written disclosure when reviewing the claims for compliance with the requisite patent regulations and statutory requirements.

At page 37, lines 19-25 and at page 49, line 28 through page 50, line 6 of the specification, it is clear that the terms "multifactorial" and "nonspecific" are utilized as adjectives to characterize growth factors, such as stem cells. This fact is included in the Fifth Supplemental Information Disclosure Statement ("IDS") filed October 21, 2004, (attached hereto as Exhibit B), which crossed in the mail with the October 18, 2004 Final Rejection. It is beyond reasonable dispute that one reading the dictionary references in the IDS would conclude that "multifactorial" and "nonspecific" are adjectives denoting characters and qualities of cells.

The Examiner, in the Final Rejection, alleged that the art only uses such terms to describe causes, effects, and processes. Obviously, such allegation flies in the face of conventional medical terminology. These terms are used throughout Petitioner's specification in a manner consistent with the definitions contained in Exhibit B. The Examiner's erroneous understanding of these terms goes to the core of the issue as to whether or not the present claims are embraced by the elected invention.

The Examiner's second major technical misunderstanding is in alleging that stem cells are not living organisms. In fact, the Examiner stated at page 6 of the Final Rejection that,

“While Petitioner may be his own lexicographer, to define a living organism as encompassing stem cells is repugnant to the meaning of ‘living organism’ found in the art. Such is improper.” The Examiner also alleged that, “...the art defines ‘living organism’ as independent,” and that, “Stem cells are part of a living organism, but are not living organisms, *per se*.” All of the above allegations are factually incorrect and at variance with accepted usage in the medical arts to which the present invention is directed. What we have here is a case where the Examiner chose to become her own lexicographer rather than simply considering such terms in light of Petitioner’s specification and highly reputable medical publications.

In the Response of August 18, 2004, Petitioner provided evidence that cells are living organisms. That stem cells are clonogenic and clones are living organisms are such well-established biological tenets, that official notice should be taken of these facts. In any event, clonogenic means the cells generate identical copies of themselves. Based on the aforesaid information cited in the Response, it is irrefutable that cells, including stem cells, are living organisms. The Examiner responded to this statement by agreeing that the term “clone” can refer to pieces of nucleic acid, cells, or entire living organisms but did not accept this evidence on the basis that cells, while alive, are not necessarily a living organism. The Examiner further stated that living organisms must be independent. In addressing this issue, the Examiner admits the well-established fact that cells are clones. If clones are living organisms, cells must also be living organisms because cells routinely clone. Moreover, the On-line Medical Dictionary published at the Dept. of Medical Oncology, University of Newcastle upon Tyne (attached hereto as Exhibit C) includes the following definition:

Clone – a propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

Obviously, from this definition, a living organism can consist of a single cell.

In any event, the glossary posted on the Biospace website, [www.biospace.com](http://www.biospace.com) (attached hereto as Exhibit D), contains a definition of "cell" provided by the National Institutes of Health and demonstrates that a single cell is a living organism. The definition is as follows:

Cell – it is a small, watery membrane-bound compartment filled with chemicals and a complete copy of the organism's genome. All living organisms are made of one or more cells.

The above definitions clearly evince that the Examiner's narrow definition of "living organism" is contrary to knowledge understood in the medical arts.

The Examiner has patently mischaracterized the nature and meaning of the well-recognized medical terms "multifactorial," "nonspecific," and "living organism." The Examiner's multifarious restriction requirements based upon technically inaccurate information have further prolonged prosecution and are tantamount to denying Petitioner procedural due process. Giving the above terms their correct medical meaning, it is clearly evident that claims 382-388 fall within Petitioner's elected invention and that an action examining such claims should have been provided by the Examiner. Petitioner believes that it is entitled to a full, complete action on the merits of such claims.

In view of the above remarks and evidence, Petitioner hereby respectfully requests the following relief:

1. The Examiner be instructed to withdraw the objection to claims 382-388;
2. The Examiner be instructed to construe the restriction requirement in light of Petitioner's specification and in accordance with conventional medical terminology and thereby construe Petitioner's elected specie to include claims 382-388;

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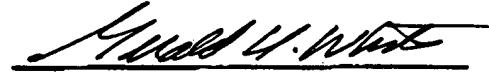
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PATENT APPL. NO. 09/064,000

3. The Examiner be instructed to withdraw the Final Rejection as being premature and issue a new, non-final action on the merits for claims 382-388; and
4. Petitioner respectfully requests an oral hearing to further address this matter. It is suggested that Petitioner's attorneys, Gerald K. White and Charles N. Lovell, attend any hearing, along with Examiner Elizabeth C. Kemmerer, Ph.D., and the Supervising Primary Examiner, Brenda Brumback, Ph.D. Petitioner believes that a hearing could serve to place the application on track and also expedite its prosecution. This objective is especially important to Petitioner in view of the above-discussed term erosion situation.

Respectfully submitted,

Date: November 4, 2004



Gerald K. White  
Reg. No. 26,611  
Attorney for Petitioner

Date: November 4, 2004



Charles N. Lovell  
Reg. No. 38,012  
Attorney for Petitioner

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Email: [gkwhite@pol.com](mailto:gkwhite@pol.com)

## **EXHIBIT A**

**CLAIMS 382-388**

382. A method for producing a desired soft tissue in a body of a human patient comprising:

- (a) Placing cells in said body of said human patient;
- (b) Forming a bud in said body of said human patient; and
- (c) Growing said desired soft tissue from said bud.

383. The method of claim 382, wherein said cells are multifactorial and non-specific.

384. The method of claim 383, wherein said cells comprise stem cells.

385. The method of claim 382 further comprising forming a new artery.

386. The method of claim 383 further comprising forming a new artery.

387. The method of claim 382, wherein said soft tissue comprises mesodermal tissue.

388. The method of claim 382, wherein said soft tissue comprises an artery.

**EXHIBIT  
B**

**FIFTH SUPPLEMENTAL  
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STATEMENT**

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TO:	Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450		
ATTN:	Examiner Elizabeth Kemmerer, Ph.D. Art Unit 1646		
FAX NO.:	(703) 872-9308		
FROM:	Gerald K. White		
RE:	Patent Application Serial No. 09/064,000 Applicant: James P. Ellis Filed: April 21, 1998 Title: METHOD AND APPARATUS FOR INSTALLATION OF DENTAL IMPLANT		
<hr/> <p>Sir:</p> <p>Enclosed is Applicant's Fifth Supplemental Information Disclosure Statement (including Certification), Form PTO-1448 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).</p> <p>Respectfully submitted,</p> <p><i>Gerald K. White</i>  Gerald K. White  Reg. No. 28,611  Attorney for Applicant</p>			
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**ATTN:** Examiner Elizabeth Kemmerer, Ph.D.  
Art Unit 1646

**FAX NO.:** (703) 872-9306

**FROM:** Gerald K. White

**RE:** Patent Application Serial No. 09/064,000  
Applicant: James P. Elia  
Filed: April 21, 1998  
Title: METHOD AND APPARATUS FOR  
INSTALLATION OF DENTAL IMPLANT

---

Sir:

Enclosed is Applicant's **Fifth Supplemental Information Disclosure Statement** (including Certification), Form PTO-1449 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).

Respectfully submitted,

Gerald K. White  
Reg. No. 26,611  
Attorney for Applicant

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PATENT  
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia )  
Serial No.: 09/064,000 ) Group Art Unit: 1646  
Filed: April 21, 1998 ) Examiner: Elizabeth Kemmerer, Ph.D.  
For: METHOD AND APPARATUS )  
FOR INSTALLATION OF )  
DENTAL IMPLANT )

**FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
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Arlington, VA 22313-1450

Sir:

Enclosed herewith, please find Form PTO-1449 (Modified) pertaining to the above-identified application. A copy of each of the publications listed thereon (References ABY-ABZ) is enclosed.

This Fifth Information Disclosure Statement (IDS) is submitted to address an issue raised by the Examiner regarding the meaning of the terms "multifactorial" and "nonspecific cells." While Applicant believes that it has used such terms properly and that one skilled in the art would fully comprehend the meaning of such terms, dictionary definitions are included to further acquaint the Examiner with such terms as they are used in the medical arts.

As will be noted from References ABY and ABZ, "multifactorial" and "nonspecific" are adjectives that denote qualities and characterizations of cells.

“Multifactorial” means: “involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)”

“Nonspecific” means: “...undestined, undetermined, undifferentiated,...”

It is clear from a reading of the patent application, the qualities and characteristics of multifactorial and nonspecific cells can be found in cells such as: stem cells, germinal cells, and pluripotent cells.

No one skilled in the art would question that a fundamental property of all of these cells is that they are undifferentiated.

Also, no one skilled in the art would question that the state of being known as “pluripotent” permits a cell to be capable of affecting more than one organ or tissue. A cell’s capability to affect more than one tissue or organ involves or depends upon several factors or causes and can result from the interaction of many genes.

This IDS is being submitted in an effort to reduce the number of issues in the instant application and thereby expedite the prosecution thereof.

No fee is believed to be due because Applicant and Applicant’s attorney were not aware of such patent more than three (3) months prior to this submission. A certification including such facts is enclosed.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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For: METHOD AND APPARATUS )  
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**CERTIFICATION**

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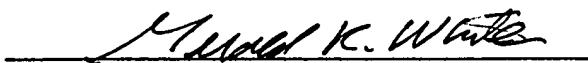
Sir:

I, Gerald K. White, Attorney for Applicant, hereby state that the two references cited in this Fifth Supplemental Information Disclosure Statement ("IDS") were first discovered by me less than three (3) months prior to the date set forth below.

I further state that no item of information contained in this Fifth Supplemental IDS was cited in a written communication from a foreign patent office in a counterpart foreign application, and, to my knowledge, after making reasonable inquiry, no item of information contained in this Fifth Supplemental IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three (3) months prior to the filing of this statement.

Respectfully submitted,

Date: October 21, 2004

  
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Reg. No. 26,611

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Docket No.:

Serial No.: 09/064,000

Group No.: 1646

Filing Date: April 21, 1998

Examiner: Elizabeth Kemmerer, Ph.D.

Applicant: James P. Elia

**Reference Designation U.S. PATENT DOCUMENTS**

Examiner initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)

**Foreign Patent Documents**

		Document Number	Date	Country	Class	Sub-Class	Translation Yes No

**Other Art (including author, title, date, pertinent pages, etc.)**

	ABY	<a href="http://www.dictionary.net">http://www.dictionary.net</a> definition of "multifactorial"
	ABZ	<a href="http://www.dictionary.net">http://www.dictionary.net</a> definition of "nonspecific"

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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P. 2



What does multifactorial mean?

**multifactorial** adj : involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)

Source: WordNet (r) 2.0

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p. 3

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What does nonspecific mean?

nonspecific adj : not caused by a specific agent; used also of staining in making microscope slides; "nonspecific entities" [ant: specific, specific]

Source: WordNet (r) 2.0

58 Moby Thesaurus words for "nonspecific": abstract, aleatory, amorphous, bland, blobby, blurred, blurry, broad, chance, chancy, chaotic, collective, confused, disordered, featureless, foggy, fuzzy, general, generalized, generic, hit-or-miss, ill-defined, imprecise, inaccurate, inchoate, indecisive, indefinable, indefinite, indeterminate, indistinct, inexact, lax, loose, nebulous, neutral, obscure, orderless, random, shadowed forth, shadowy, shapeless, stochastic, sweeping, uncharactenized, unclear, undefined, undetermined, undifferentiated, unspecified, unplain, unspecified, vague, veiled, wide

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## **EXHIBIT C**

### **ON-LINE MEDICAL DICTIONARY**

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clone from On-line Medical Dictionary

4804881674

p.5

Page 1 of 1



## clone

<cell biology> A propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

(18 Nov 1997)

---

Previous: [clonal expansion](#), [clonal selection](#), [clonal selection theory](#), [clonazepam](#)  
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## **EXHIBIT D**

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Biospace Glossary: Definitions

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**Cell** © BASIC

The basic unit of any living organism.

**Full Definition**  
It is a small, watery, membrane-bound compartment filled with chemicals and a complete copy of the organism's genome. All living organisms are made of one or more cells.

**See Also**

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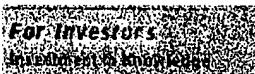
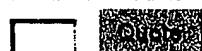
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## Biospace Glossary: Definitions

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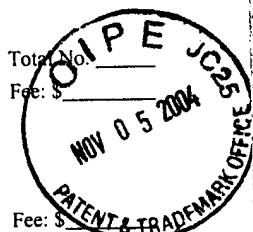
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## **Stem Cells**

Stem cells are essentially undifferentiated cells. There are many kinds of stem cells, some more differentiated than others. When they divide, their progeny mature and specialize into a specific type of cell (i.e. heart, blood, liver). These differentiated cells form an embryo. Stem cells also exist in adults (Adult Stem (AS) cells) and are used to repair and regenerate damaged organs and tissues throughout life. However, in adults the repair and regeneration by stem cells is limited to only certain cell types. In contrast, embryonic stem (ES) cells are not limited in their potential to differentiate into every cell type. Embryonic germ (EG) cells have the same potential as ES cells. It is the versatility and nonspecificity of these cells that gives them the potential to have therapeutic applications.

Related Topics:

 **Genetics**

Contributed by: BU

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**ASSOCIATES**

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**Henry W. Tarring, Esq.\* - Patents**

**\*Member of Virginia Bar**

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Attorney for Applicant

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In Re Application of: James P. Elia )  
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Sir:

I, Gerald K. White, Attorney for Applicant, hereby state that the two references cited in this Fifth Supplemental Information Disclosure Statement ("IDS") were first discovered by me less than three (3) months prior to the date set forth below.

I further state that no item of information contained in this Fifth Supplemental IDS was cited in a written communication from a foreign patent office in a counterpart foreign application, and, to my knowledge, after making reasonable inquiry, no item of information contained in this Fifth Supplemental IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three (3) months prior to the filing of this statement.

Respectfully submitted,

Date: October 21, 2004

  
Gerald K. White  
Reg. No. 26,611

List of Patents and Publications For  
**Applicant's 5<sup>th</sup> Supplemental Information Disclosure Statement**  
**Page 1 of 1**

Form PTO-1449 (Modified)  
 (Use several sheets if necessary)



Docket No.:

Serial No.: 09/064,000

Group No.:

1646

Filing Date: April 21, 1998

Examiner:

Elizabeth Kemmerer, Ph.D.

Applicant: James P. Elia

**Reference Designation U.S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)

**Foreign Patent Documents**

		Document Number	Date	Country	Class	Sub-Class	Translation Yes No

**Other Art (including author, title, date, pertinent pages, etc.)**

	ABY	<a href="http://www.dictionary.net">http://www.dictionary.net</a> definition of "multifactorial"
	ABZ	<a href="http://www.dictionary.net">http://www.dictionary.net</a> definition of "nonspecific"

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



What does multifactorial mean?

multifactorial adj : involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)

Source: WordNet (r) 2.0

[multifactorial](#)

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What does nonspecific mean?

nonspecific adj : not caused by a specific agent; used also of staining in making microscope slides; "nonspecific entities" [ant: [specific](#), [specific](#)]

Source: WordNet (r) 2.0

58 Moby Thesaurus words for "nonspecific": abstract, aleatoric, aleatory, amorphous, bland, blobby, blurred, blurry, broad, chance, chancy, chaotic, collective, confused, disordered, featureless, foggy, fuzzy, general, generalized, generic, hazy, hit-or-miss, ill-defined, imprecise, inaccurate, inchoate, incoherent, indecisive, indefinable, indefinite, indeterminate, indistinct, inexact, lax, loose, nebulous, neutral, obscure, orderless, random, shadowed forth, shadowy, shapeless, stochastic, sweeping, uncharacterized, unclear, undefined, undetermined, undifferentiated, unplain, unspecified, vague, veiled, wide

Source: Moby Thesaurus II by Grady Ward, 1.0

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